

THAT WHICH IS CLAIMED:

1. A composition comprising:  
(a) an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue,  
5 wherein the IGF-I or IGF-I analogue is soluble in said composition at a concentration  
of at least about 12 mg/ml when said composition is at a temperature of about 4°C;  
and  
(b) a solubilizing compound comprising a guanidinium group;  
wherein said composition has a pH of at least about pH 5.5.

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2. The composition of claim 1, wherein said solubilizing compound is  
arginine or an arginine analogue.

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3. The composition of claim 1, wherein said solubilizing compound is  
guanidine hydrochloride.

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4. The composition of claim 1, wherein said solubilizing compound is  
present in a molar concentration range from about 10 mM to about 1 M.

5. The composition of claim 1, wherein said solubilizing compound is  
present in a molar concentration range from about 15 mM to about 500 mM.

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6. The composition of claim 1, wherein said solubilizing compound is  
present in a molar concentration range from about 20 mM to about 200 mM.

7. The composition of claim 1, wherein said pH is in a range from about  
pH 5.5 to about pH 9.0.

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8. The composition of claim 1, wherein said pH is in a range from about  
pH 5.7 to about pH 6.3.

9. The composition of claim 1, wherein said pH is about pH 6.0.

10. The composition of claim 1, wherein said IGF-I or IGF-I analogue is present in said composition in a concentration of about 12 mg/ml to about 200 mg/ml.

5 11. The composition of claim 1, wherein said IGF-I or IGF-I analogue is present in said composition in a concentration of about 15 mg/ml to about 200 mg/ml.

12. The composition of claim 1, wherein said IGF-I or IGF-I analogue is present in said composition in a concentration of about 25 mg/ml to about 200 mg/ml.

10 13. The composition of claim 12, wherein said composition comprises sodium chloride at a molar concentration of about 150 mM.

14. The composition of claim 1 comprising a buffer selected from the group consisting of a glutaric acid buffer, a maleic acid buffer, a succinic acid buffer, 15 a citric acid buffer, imidazole, and a histidine buffer.

15. A composition comprising:  
(a) an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue, where in the IGF-I or IGF-I analogue is soluble in said composition at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C;  
(b) a solubilizing compound selected from the group consisting of arginine, an arginine analogue, and guanidine hydrochloride; and  
(c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

25 16. The composition of claim 15, further comprising sodium chloride at a molar concentration of about 150 mM.

30 17. A method of making an IGF-I composition comprising:  
(a) providing an amount of an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue such that the IGF-I or IGF-I analogue is soluble in said composition at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C; and

(b) combining the IGF-I or IGF-I analogue with a solubilizing compound comprising a guanidinium group; wherein the pH of the composition is about pH 5.5 to about pH 9.0.

5            18. A method of delivering IGF-I to a vertebrate subject comprising:  
              (a) providing a composition according to claim 1; and  
              (b) administering said IGF-I composition to said vertebrate subject.

10            19. The method of claim 18, wherein the administering is parenteral.

15            20. A method of enhancing the solubility of an insulin-like growth factor-1 (IGF-I) or an IGF-I analogue in a composition having a pH of about pH 5.5 to about 9.0, said method comprising combining IGF-I or an IGF-I analogue with an amount of a solubilizing compound that comprises a guanidinium group sufficient to increase the solubility of IGF-I or the IGF-I analogue relative to the solubility of IGF-I or the IGF-I analogue in the absence of the solubilizing compound.

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